

REMARKS

Applicant hereby requests further consideration of the application in view of the comments that follow. This response is submitted in reply to the Office Action mailed June 14, 2007 ("the Action"). Claims 1-32 stand rejected in the application.

I. The §112, First Paragraph Rejections

The Action rejects Claims 1-20, 24, 25, 29 and 30 for failing to comply with the written description requirement. More particularly, the Action alleges that Claim 1 raises written description rejections because certain added claim features were not described in the specification in such a way as to "reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. For example, the Examiner says that the "displaying a plurality of the adjusted MRI cine loops at a clinician workstation in substantially real-time while the patient is in an MRI scanner used for the acquiring step" is not clearly pointed out in the specification. The Examiner concedes that para. 49 details near real-time display, and that it can be inferred that *perhaps* the patient remains in the scanner while the clinician reviews the cine loops, but "this is not necessarily inferred, as the disclosure is not specific to the details of the patient or scanner." Action, p. 2.

Applicant respectfully disagrees. Applicant submits that the application does provide sufficient support that reasonably conveys to one of skill in the art that the inventors had possession of the claimed invention. The specification recites at p. 13:

In particular embodiments of the present invention, the display of cine loops is provided in real time. In other embodiments, the display of cine loops is provided in near real time. Such real time or near real time display of cine loops of a patient undergoing stress testing may be utilized to provide safe stress testing by allowing for rapid analysis and monitoring of the stress test such that patient injury may be avoided.

The specification also states at page 12, lines 7-11, that the evaluation process can be performed in a sufficiently real-time manner so as to allow a physician to utilize the MRI cine loops to monitor a stress test while the stress test is being performed. Applicant

respectfully submits that at least the above text clearly convey that the patient is in the scanner during the clinician evaluation; otherwise, how can the stress test be monitored and the rapid analysis be carried out (*e.g.*, the administration of additional stress inducing agents)?

Claims 24 and 25 are also rejected for lack of support in the written description. Claim 24 recites that the adjustable feature of the display level is the opacity, but the Action says the description does not include this feature. Applicant submits that page 14 of the specification states that user input can be used to crop a cine loop image and/or to adjust contrast, brightness, gamma or other display levels. Thus, Applicant respectfully submits that it is at least inherent that the system can also adjust opacity. However, to advance prosecution Applicant has canceled this term from Claim 24.

With respect to Claim 25, Applicant agrees that the specification does not specifically state that the system works without MR fluoroscopy, but Applicant also submits that an overall reading of the application makes it very clear that the MRI images are based on contrast and/or stress agents as a replacement for ultrasound and nuclear perfusion stress test (page 2 and page 3 of the background) and does not require MR fluoroscopy. However, to advance prosecution, Applicant has removed this recitation from Claim 25.

The Action rejects Claim 29 because it details registering a common physical location of the heart in the MRI cine loops before the step of comparing. The Action states that the application does not describe registration of loops in relation to common physical locations of the heart, nor is it specific to take place prior to comparison. However, at p. 12 (last para.), the application states that registration of baseline loops to cine loops can be provided such that corresponding pixels are associated with the same physical location. This paragraph is a discussion of comparison of the images, so of course the registration takes place prior to the comparison. While Applicant believes that the specification sufficiently supports this claim as written, Applicant has amended Claim 29 in a non-narrowing manner to more closely correspond to the text at p. 12.

With respect to Claim 30, the Examiner also states that the user touch screen feature is not specifically described in the specification. While Applicant believes that this feature is

sufficiently supported by Figure 6, Applicant has amended Claim 30 in a non-narrowing manner to advance prosecution.

In view of the foregoing, Applicant respectfully submits that the claims comply with the written description requirement and requests that these rejections be withdrawn.

II. The Art Rejections

The Action continues to reject the pending claims as being obvious over the previously cited prior art: namely, U.S. Patent No. 5,619,995 to Lobodzinski ("Lobodzinski") over U.S. Patent 5,997,883 to Epstein ("Epstein") or another secondary reference. The Action states at page 4 that the arguments presented regarding (a) the ability to recognize early evidence of inducible ischemia and (b) that a cine loop is representative of typical images of the heart averaged over many heart beats versus "real time video stream" of heart beats are not claimed.

Applicant has amended Claim 1 to recite that the cine loops are displayed during the stress test to allow a physician to assess cardiac physiology of a patient so as to adjust parameters of the test and/or avoid injury to the patient thereby providing safer cardiac stress testing. Such monitoring can provide early evidence of inducible ischemia to allow a physician to assess cardiac physiology of a patient so as to adjust parameters of the test and/or avoid injury to the patient, thereby providing safe stress testing as described for example, at pp.12 and 13.

Regarding the issue of how MRI cine loops operate, Applicant submits that it is well-known that MRI cine loops are averaged over many heart beats. *See, e.g., Quantification of cardiac function by conventional and cine magnetic resonance imaging*. Sechtem U, Pflugfelder P, Higgins CB. *Cardiovasc Intervent Radiol*. 1987;10(6):365-73. Applicant submits that MRI cine loops are created by electronically combining acquired data from corresponding positions of the heart during multiple cardiac cycles and those of skill in the art clearly understand this operational detail. Multiple heartbeats are required in order to collect enough data at each corresponding position of the heart to allow creation of complete images. Embodiments of the present invention now generate the cine loops using multiple MRI

images during a cardiac cycle that form the frames of a cine loop -- not a real-time video stream, during a stress test in a manner that allows for safe and more accurate cardiac stress tests. Applicant has amended Claim 1 to recite that the MRI cine-loops are generated using multiple MRI images that form the frames of the cine loops (*see, e.g.*, p. 7, line 25 and p. 8, line 8, of the specification). Applicant reiterates that the generation of substantially real-time MRI cine loops to allow for improved safety during cardiac stress testing is novel and non-obvious over the cited prior art.

As noted at page 11, lines 27-31, of the application, temporal synchronization of the cine loops has been found to allow physicians to evaluate cardiac physiology more effectively without introducing artifacts and/or distortions through the temporal synchronization process that would obscure information or provide false information that would lead to invalid evaluations.

Again, Applicant respectfully emphasizes the technical differences between video streams and MRI cine loops (as was also noted by Lobodzinski). MRI cine loops are defined by electronically combining image data from single frame images of the same respective view of the heart at various points in time of cardiac cycles. Further, Lobodzinski fails to teach or suggest providing synchronized, adjusted MRI cine loops that are displayed in substantially real-time, much less while a patient is in an MRI scanner (*see, e.g.*, page 12, Figure 5 of the pending application). Also, with respect to the fact that Lobodzinski states that MRI may be used, Applicant respectfully submits that, in the past, the MRI cine loops for cardiac stress analysis were asynchronous; that is, the MRI data for the cine loops was collected, then manipulated at a later time. At col. 2, line 4, Lobodzinski states nothing other than "most diagnostic imaging systems provide some sort of cine loop review." Notably, Lobodzinski goes on to also state that, "they typically do not provide digital motion video recording, serial comparison, and display functions" (emphasis added).

III. New Dependent Claims

Applicant has added new dependent Claims 33 and 34. The claims are directed to the rapid switching between displays of different locations of the same dose or different doses of

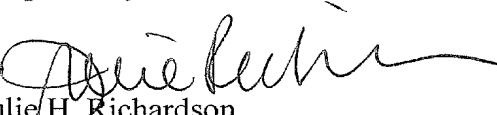
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the same location, thus allowing a physician to rapidly switch between the various display mechanisms when evaluating the MRI cine loops (*see, e.g.*, p. 14, lines 4-6). This configuration of the system allows the physician to switch between the selected views substantially instantaneously, thereby allowing him/her to focus on the images rather than waiting for the presentation to change, thereby providing easier view comparison. Applicant respectfully submits that these claims are patentable over the cited prior art.

CONCLUSION

Accordingly, Applicant submits that the present application is in condition for allowance and the same is earnestly solicited. Should the Examiner have any matters outstanding of resolution, she is encouraged to telephone the undersigned at 919-854-1400 for expeditious handling.

Respectfully submitted,


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